DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/11/11 has been entered.

Claims 1-8, 10-14 and 18 are under examination.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8, 10-14 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goldstein et al (WO 03/020215).

The instant invention is drawn to a method of treating, or reducing extracelluar maxtrix build-up in a body tissue (specifically coronary tissue) comprising administering thymosin beta 4 or oxidized TB4.

Goldstein et al. discloses a method of treatment of tissue comprising administering thymosin beta 4. See, for example, claims 1-5, 9-10, 12 and 15. Golstein et al. discloses administration may include intravenous, intraperitoneal, intramuscular or subcutaneous injections, or inhalation, transdermal or oral administration of the composition containing thymosin beta 4. See, for example, page 3, lines 29-31. Goldstein et al. discloses other proteins useful in the method of treatment, such proteins are LKKTET, TB9, TB10, TB11, TB12, TB13, TB14, Tb15, gelsolin, DBP, profiling, cofilin, adservertin, propomyosin, fincilin, depactin, vilin, fragmin, severin, and acumentin. See, for example, page 4, lines 7-34.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to administer the peptide agent in conjunction with the utilization of a stent or cardiac catheterization, or in combination with a plaque reducing agent or cholesterol reducing agent, based upon the overall beneficial teachings provided by Goldstein, as discussed above. If not expressly taught, the result-effective adjustment of conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments were fully considered but were not found persuasive. Applicant contends that the instant claims are directed to treating a group of subjects that is not contemplated by the cited reference. However, the examiner contends that the cited reference is drawn to methods of treatment related to changes that occur before, during or after a myocardial (coronary) event by the administration of thymosin beta 4 or oxidized thymosin beta 4. The instant specification discloses plaque and extracellular matrix build-up in body tissues and vessels, including myocardial and coronary vessels. See, for example, page 1, paragraph 3. The instant claims treat this build up with the administration of thymosin beta 4 or oxidized thymosin beta 4. The instantly claimed functional effects would necessarily flow from the administration of the instantly claimed composition to a patient in need thereof, as taught by Goldstein. "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." See MPEP 2112.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROY TELLER whose telephone number is (571)272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0971. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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/Christopher R Tate/
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